

#350  
PD

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA  
FILED IN CAMERA & UNDER SEAL

UNITED STATES OF AMERICA ;  
THE STATES OF CALIFORNIA,  
DELAWARE, FLORIDA, GEORGIA,  
ILLINOIS, INDIANA, HAWAII,  
LOUISIANA, MASSACHUSETTS,  
MICHIGAN, MONTANA, NEW  
HAMPSHIRE, NEW MEXICO, NEW  
YORK, NEVADA, TENNESSEE,  
TEXAS, VIRGINIA, CITY OF NEW  
YORK, CITY OF CHICAGO AND  
THE DISTRICT OF COLUMBIA  
*ex rel.* GERARDO TORRES, M.D.,

Relator-Plaintiff

v.

SHIRE SPECIALTY  
PHARMACEUTICALS; SHIRE PLC;  
SHIRE US, INC.; SHIRE  
PHARMACEUTICALS, INC.; SHIRE,  
LLC; SHIRE DEVELOPMENT, INC.;  
AND SHIRE US MANUFACTURING,  
INC.,

Defendants.

JURY TRIAL DEMANDED

CIVIL ACTION NO. 08 4795 !

COMPLAINT FOR VIOLATIONS OF THE  
FEDERAL FALSE CLAIMS ACT [31 U.S.C.  
§3729 *et seq.*]; CALIFORNIA FALSE CLAIMS  
ACT [Cal. Gov. Code §12650 *et seq.*];  
DELAWARE FALSE CLAIMS & REPORTING  
ACT [6 Del. C. §1201 *et seq.*]; DISTRICT OF  
COLUMBIA PROCUREMENT REFORM  
AMENDMENT ACT [D.C. Code Ann. §1-  
1188.14 *et seq.*]; FLORIDA FALSE CLAIMS  
ACT [Fla. Stat. Ann. §68.081 *et seq.*]; ILLINOIS  
WHISTLE BLOWER REWARD &  
PROTECTION ACT [740 ILCS § 175 *et seq.*];  
HAWAII FALSE CLAIMS ACT [Haw. Rev Stat §  
661-21(a)(3)]; MONTANA FALSE CLAIMS  
ACT; [Mont. Code Ann. §17-/-410, Mont. Code  
Ann § 17-8-403]; INDIANA FALSE CLAIMS  
ACT AND WHISTLEBLOWERS PROTECTION  
ACT [Ind. Code Ann. §5-11-5.5-1-5-11-5.5-18];  
MICHIGAN MEDICAID FALSE CLAIMS ACT  
[Mich. Comp Laws § 400.603,606 and 607]; NEW  
HAMPSHIRE FALSE CLAIMS ACT [New  
Hamp. Stat. 167:61-b]; LOUISIANA FALSE  
CLAIMS ACT [La. Rev. Stat. Ann. § 46:439.1 *et  
seq.*]; MASSACHUSETTS FALSE CLAIMS ACT  
[Massachusetts Gen. Laws c.12 §5(A)]; NEW  
MEXICO MEDICAID FALSE CLAIMS ACT  
[N.M. Stat. Ann. § 27-14-1-27-14-15]; NEVADA  
FALSE CLAIMS ACT [Nev. Rev. Stat. Ann.  
§357.010 *et seq.*]; TENNESSEE MEDICAID  
FALSE CLAIMS ACT [Tenn. Code Ann. §71-5-  
181 *et seq.*]; TEXAS MEDICAID FRAUD  
PREVENTION ACT [Tex. Human Res. Code, Ch.  
36, §36.101 *et seq.*]; VIRGINIA FRAUD  
AGAINST TAXPAYERS ACT [Va. Stat. Ch. 842,  
Art. 19.1, §8.01-216.1 *et seq.*]; GEORGIA STATE  
MEDICAID ACT [Ga. Code 49-4-168 *et seq.*];  
NEW YORK FALSE CLAIMS ACT [N.Y. St.  
Finance Law §187 *et seq.*]; NEW YORK CITY  
FALSE CLAIMS ACT [New York City  
Administrative Code §7-801-§7-810]; CHICAGO  
FALSE CLAIMS ACT [Municipal Code of  
Chicago §1-22-010-§1-22-060]; NEW JERSEY  
FALSE CLAIMS ACT [N.J. STAT. § 2A:32C-1-  
17];

FILED

OCT 7 2008

MICHAEL E. RUENZ, Clerk  
By fu Dep. Clerk

## **COMPLAINT**

Relator-Plaintiff Gerardo Torres, M.D. ("Relator-Plaintiff"), through his undersigned attorneys, on behalf of the United States of America ("United States"), and the State of California, the State of Delaware, the State of Florida, the State of Georgia, the State of Illinois, the State of Hawaii, the State of Indiana, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of New Mexico, the State of Montana, the State of New Hampshire, the State of New York, the State of Nevada, the State of Tennessee, the State of Texas, and the Commonwealth of Virginia, the State of New Jersey, the City of New York, the City of Chicago, in addition to the District of Columbia (collectively, "the States and Cities"), for his Complaint against Defendants Shire Specialty Pharmaceuticals; Shire plc; Shire US, Inc.; Shire Pharmaceuticals, Inc.; Shire LLC; Shire Development, Inc.; and Shire US Manufacturing, Inc. (collectively, "Shire" or "Defendant"), alleges as follows:

### **I. INTRODUCTION**

1. This is an action, by and through Relator-Plaintiff Gerardo Torres, M.D., to recover treble damages and civil penalties on behalf of the United States and the States and Cities arising from false and/or fraudulent records, statements and claims made, used and/or caused to be made, used or presented by Defendant and/or its agents, and employees in violation of the federal False Claims Act, 31 U.S.C. § 3729 *et seq.* and the state laws referred to in paragraph 2 of this Complaint.

2. Defendant's acts also constitute violations of the California False Claims Act, Cal. Gov. Code §12650 *et seq.*; the Delaware False Claims & Reporting Act, 6 Del. C. §1201 *et seq.*; the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §1-1188.14 *et seq.*; the Florida False Claims Act, Fla. Stat. Ann. §68.081 *et seq.*; the Georgia State

PD

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA  
FILED IN CAMERA & UNDER SEAL

1

UNITED STATES OF AMERICA ;  
THE STATES OF CALIFORNIA,  
DELAWARE, FLORIDA, GEORGIA,  
ILLINOIS, INDIANA, HAWAII,  
LOUISIANA, MASSACHUSETTS,  
MICHIGAN, MONTANA, NEW  
HAMPSHIRE, NEW MEXICO, NEW  
YORK, NEVADA, TENNESSEE,  
TEXAS, VIRGINIA, CITY OF NEW  
YORK, CITY OF CHICAGO AND  
THE DISTRICT OF COLUMBIA  
*ex rel.* JOHN DOE,

JURY TRIAL DEMANDED

CIVIL ACTION NO. 08 4798

COMPLAINT FILED UNDER SEAL

Relator-Plaintiff

v.

JOHN DOE COMPANIES

Defendants.

False Medicaid Claims Act, Ga. Code 49-4-168 *et seq.*; the Illinois Whistle Blower Reward & Protection Act, 740 ILCS § 175 *et seq.*; the Hawaii False Claims Act, Haw Rev. Stat. § 661-21(a)(3); the State of Indiana False Claims And Whistleblowers Protection Act, Ind. Code Ann. § 5-11-5.5-1-5-11-5.5-18; the Louisiana False Claims Act, La. Rev. Stat. Ann. § 46:439.1 *et seq.*; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5 *et seq.*; the State of Michigan Medicaid False Claims Act, Mich. Comp Laws § 400.603,606 and 607; the State of Montana False Claims Act, Mont. Code Ann. § 17-8-403,17-8-410; the State of New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1-27-14-15; the New Hampshire False Claims Act, New Hamp. Stat. 167:61-b; the New York False Claims Act, N.Y. St. Finance Law §187 *et seq.*; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §357.010 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §71-5-181 *et seq.*; the Texas Medicaid Fraud Prevention Act, Tex. Human Res. Code, Ch. 36, §36.101 *et seq.*; the City of New York False Claims Act, New York City Administrative Code §7-801-§7-810; the City of Chicago False Claims Act, Municipal Code of Chicago §1-22-010-§1-22-060; the New Jersey False Claims Act N.J. STAT. §2A:32C-1-17; and the Virginia Fraud Against Taxpayers Act, Va. Stat. Ch. 842, Art. 19.1, §8.01-216.1 *et seq.* (collectively, the “State False Claims acts”).

3. This matter involves illegal marketing practices by Defendant Shire.

4. On information and belief, since at least 2001, Defendant Shire has been engaged in illegal marketing schemes for, among other things, the purpose of increasing the sale of its drugs Adderall XR® (mixed amphetamine salts) and Vyvanse® (lisdexamfetamine dimesylate).

5. Both Adderall XR and Vyvanse are amphetamines indicated for the treatment of attention deficit hyperactivity disorder (“ADHD”).

6. Relator-Plaintiff Gerardo Torres, M.D. is the Vice President, Research and Development, ADHD/CNS Business Unit for Shire.

7. Dr. Torres is responsible for the development and execution of global development plans for Shire's ADHD/CNS business unit and the development and execution of global medical plans to support effective launches and commercialization of all business unit products.

8. Dr. Torres is also responsible for overseeing all pharmacovigilance and epidemiology efforts at Shire which includes interacting with the FDA and foreign regulatory agencies.

## **II. PARTIES**

9. The United States of America, and the above-named States and Cities, are the plaintiffs for whom recovery is sought for false and fraudulent claims submitted to Medicaid and other government-funded health programs, including Champus/TriCare and Veteran's Administration funded programs, as well as those of the respective State and City plaintiffs.

10. Relator-Plaintiff Gerardo Torres, M.D. is the Vice-President of Research and Development for Shire and is a citizen and resident of the Commonwealth of Pennsylvania. He brings this action on his own behalf and on behalf of the United States pursuant to 31 U.S.C. § 3730(b)(1) and the respective State whistleblower statutes cited in paragraph 2 of this Complaint.

11. Relator-Plaintiff has worked for Shire for more than 3 years in very senior positions in the company.

12. Relator-Plaintiff Torres possesses a Master of Business Administration from Temple University and a doctorate in Medicine from the University of Puerto Rico School Of Medicine.



13. Upon information and belief, Defendant Shire Specialty Pharmaceuticals is corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with its principal place of business in Wayne, Pennsylvania.

14. Defendant Shire plc is a company organized and existing under the laws of Jersey, Channel Islands, United Kingdom.

15. Defendant Shire plc has a principal place of business in Hampshire, United Kingdom.

16. Defendant Shire plc has a principal place of business in the Republic of Ireland.

17. Defendant Shire US, Inc. is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in Wayne, Pennsylvania.

18. Defendant Shire Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Wayne, Pennsylvania.

19. Defendant Shire LLC is a limited liability company organized and existing under the laws of the State of Kentucky, with its principal place of business in Florence, Kentucky

20. Defendant Shire Development, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Wayne, Pennsylvania.

21. Defendant Shire US Manufacturing, Inc. is a corporation organized and existing under the laws of the State of Maryland, with its principal place of business in Owings Mills, Maryland.

22. Defendants Shire licenses, develops, manufactures, sells, distributes, markets and promotes Adderall XR and Vyvanse.

23. Defendant Shire licenses, develops, manufactures, sells, distributes, markets and promotes its pharmaceutical products throughout the United States, including in the Eastern District of Pennsylvania.

### **III. JURISDICTION AND VENUE**

24. This is a civil action arising under the laws of the United States to redress violations of 31 U.S.C. §§ 3729-3730. This court has jurisdiction over the subject matter of this action: (i) pursuant to 31 U.S.C. § 3732, which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730; (ii) pursuant to 28 U.S.C. § 1331, which confers federal subject matter jurisdiction; and (iii) pursuant to 28 U.S.C. § 1345, because the United States is a plaintiff.

25. This suit is not based upon prior public disclosures of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit or investigation or in a Government Accounting office or Auditor General's report, hearing, audit, or investigation, or from the news media.

26. To the extent that there has been a public disclosure unknown to Dr. Torres, Dr. Torres is an original source under 31 U.S.C. § 3730(e)(4) and the State False Claims acts. He has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the government in this Complaint.

### **IV. FACTUAL ALLEGATIONS**

27. Adderall XR is a Central Nervous System (CNS) stimulant or amphetamine, approved in the U.S. for the management of ADHD. Adderall XR is currently prescribed to thousands of adults, children, and adolescents diagnosed with ADHD.

28. In 2007, Adderall XR had sales of more than \$1.28 billion in the United States, an increase of approximately 19% for the same period in 2006.

29. Vyvanse is a prodrug of dextroamphetamine, a stimulant, and is indicated for the treatment of ADHD. It is a once-a-day treatment for adults and children who are six to 12 years old with ADHD.

30. In 2007, Vyvanse had sales of approximately \$97 million in the United States. Datamonitor, a pharmaceutical trade publication, estimates that Vyvanse's sales will reach \$1 billion by 2017. It is estimated that Vyvanse will have sales exceeding \$300 million in the United States in 2008.

31. Upon information and belief, approximately 20% of the prescriptions for Adderall XR and Vyvanse are paid for by the state and/or federal governments.

32. 78% of all ADHD prescriptions were derived from pediatric sales in 2007.

33. In order to expand the market penetration of Adderall XR and Vyvanse, Shire has engaged in a pattern of marketing each of these medications for "off-label" uses not approved by the FDA.

34. In order to effectuate its off label marketing program Shire has engaged in a scheme to make false representations as to the efficacy and safety of Adderall XR and Vyvanse.

35. There are a host of drugs indicated for the treatment of ADHD, including, but not limited to, Vyvanse, Adderall XR, Adderall (amphetamine), Concerta (extended release methylphenidate), Strattera (atomoxetine) and Ritalin (methylphenidate).

36. Upon information and belief, Shire has promoted Adderall XR as clinically superior to Adderall in numerous sales aids from at least 2001 to today. These clinical superiority claims constituted an off-label promotion.



37. Shire promoted Adderall XR being superior to Adderall in “normalizing” children with ADHD. The study referenced in support of this claim was not designed to measure the “normalization” of the children in the study. Furthermore, the authors of the study clearly averred that the study was a non-comparative study. Lastly, the comparative analysis between the drugs was a post-hoc analysis of the data. Consequently, the promotion of Adderall XR as being superior to both Adderall in “normalizing” children constituted a false and misleading promotion. Lastly, Adderall XR is not indicated to “normalize” children with ADHD.

38. There is a black box warning on each of the amphetamine based ADHD drugs that warns of the risk of dependency and abuse of the drugs. The black box warning for Adderall XR and Vyvanse reads:

**WARNING: POTENTIAL FOR ABUSE**  
AMPHETAMINES HAVE A HIGH POTENTIAL FOR ABUSE.  
ADMINISTRATION OF AMPHETAMINES FOR PROLONGED PERIODS OF  
TIME MAY LEAD TO DRUG DEPENDENCE. PARTICULAR ATTENTION  
SHOULD BE PAID TO THE POSSIBILITY OF SUBJECTS OBTAINING  
AMPHETAMINES FOR NON-THERAPEUTIC USE OR DISTRIBUTION TO  
OTHERS AND THE DRUGS SHOULD BE PRESCRIBED OR DISPENSED  
SPARINGLY. MISUSE OF AMPHETAMINES MAY CAUSE SUDDEN  
DEATH AND SERIOUS CARDIOVASCULAR ADVERSE EVENTS.

39. Of all the drugs indicated for the treatment of ADHD, only Strattera is not an amphetamine.

40. Vyvanse is a both an amphetamine and a “pro-drug”. A “pro-drug” is a pharmaceutical that is administered in an inactive form (or significantly less active). Once metabolized, the pro-drug is metabolized in the body in an active form. Despite being a pro-drug, Vyvanse still has the same black box warning as other amphetamines concerning addiction and abuse.

41. Upon information and belief, Shire sales representatives and medical science liaisons (“MSLs”) erroneously promote that Vyvanse is non-abuseable. Yet the study that supports this claim concludes that Vyvanse is subject to being abused. Consequently, any promotion that Vyvanse is “non-abuseable” constitutes an off-label promotion.

42. Moreover, such promotion and marketing represents an immediate and serious health risk to the public.

43. The health risks surrounding Adderall XR and Vyvanse are magnified because these drugs impact the central nervous system and Vyvanse can be prescribed for children.

44. Shire’s success in the promotion of Vyvanse as “non-abuseable” is memorialized in a November 2007 copied to a number of Shire high-ranking management, including Relator-Plaintiff.

45. That email discusses a presentation given by Russell Barkley, Ph.D. on November 7, 2007 at Theda Care Behavioral Health in Appleton, Wisconsin. It was reported that 800-900 people attended Dr. Barkley’s presentation.

46. Dr. Russell Barkley is an internationally-recognized authority on ADHD. Internally at Shire he is known as an “ADHD guru.”

47. According to this internal, widely-generated email, Dr. Barkley stated the following about Vyvanse:

Vyvanse is a PRO DRUG. The FDA granted this medication a new class for the treatment of ADHD. Vyvanse is unlike anything we have ever had. It’s really cool. ***You can’t abuse Vyvanse because it only is metabolized in your stomach, which is absolutely fascinating.*** What’s really interesting is that the company stumbled upon the fact that it lasts 12-14 hours. (emphasis added)

48. Upon information and belief, Dr. Barkley learned this blatantly false marketing message from Shire MSL Jennifer Robinson. It was reported that Jennifer Robinson met with Dr. Barkley four times in the year preceding Dr. Barkley's statement.

49. In fact, upon information and belief, Shire uses MSLs to promote false and misleading information about its products to key opinion leaders.

50. The "non-abuseability" message is referred to as a "branded message" by senior management at Shire.

51. Shire used medical letters that contained either false or misleading to promote both Adderall XR and Vyvanse as effective in the treatment of Conduct Disorder and Oppositional Defiant Disorder.

52. Upon information and belief, Shire promotes Adderall XR and Vyvanse for the treatment of Conduct Disorder and Oppositional Defiant Disorder. Both Conduct Disorder and Oppositional Defiant Disorder are distinct illnesses from ADHD. The promotion of Adderall XR and Vyvanse for the treatment of Conduct Disorder and Oppositional Defiant Disorder constitutes off-label promotions.

53. On September 25, 2008 the FDA issued a Warning Letter ("the Letter") to Shire for posting a video testimonial that overstated the efficacy of Adderall XR, omitted important safety information about the risks associated with Adderall XR and broadens the FDA indication for Adderall XR.

54. According to the Letter, Adderall XR has numerous contraindications, including but not limited to patients with advance arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism and patients with a history of drug abuse.

55. Also according to the Letter, Adderall XR is associated with “a number of serious risks, some of which may be fatal.” These risks “include serious cardiovascular events, hypertension, psychiatric events, aggression, long-term suppression of growth, seizures and visual disturbances.”

56. The Letter states that the webpage implies that Adderall XR reduces the likelihood or severity of the difficulties and consequences of untreated ADHD such as increased injury rates, increased sexually transmitted diseases, co-morbid conduct disorder and poor academic performance.

57. The Letter states that the video was not submitted to the FDA under cover of form FDA 2253 as required by CFR 314.81(b)(3)(i). Relator-Plaintiff has specific knowledge that Shire also failed to submit other advertising material under cover of form FDA 2253 as required by CFR 314.81(b)(3)(i).

58. Relator-Plaintiff has specific knowledge that Shire promoted Adderall XR improperly not only to viewers of the webpage but also in visual aids and other media to doctors from 2001 onwards. Specifically, Shire promoted that untreated ADHD is associated with a greater incidence of unemployment, tobacco addiction, criminal arrest, alcohol abuse and traffic violations. Concurrent promotion of these overstated data with Adderall XR implies that usage of Adderall XR will prevent a person from becoming addicted to tobacco, getting arrested, abusing alcohol, etc. This promotion, which preceded the September 29, 2008 Warning Letter, constituted a false and/or misleading promotion of Adderall XR.

59. All of Shire’s “off-label” promotional activities constituted false and fraudulent statements as a matter of law under the Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 331(a) and (b), 352(a) and (f) and regulations promulgated by the FDA to implement the FDCA.

60. Shire knew and intended that its "off-label" promotional campaign would improperly increase the submission of prescriptions for Adderall XR and Vyvanase, including those prescriptions reimbursed by the Medicare and Medicaid programs.

61. Absent Shire's illegal and improper marketing schemes, and its false statements concerning Adderall XR and Vyvanase, physicians would not have believed that it was medically prudent or necessary to write so many prescriptions for those drugs.

62. Shire's illegal and improper marketing schemes and programs have been extremely successful leading to the submission of claims to the Medicare and Medicaid programs for medically unnecessary and imprudent prescriptions which otherwise would not have been paid by Medicare and Medicaid.

63. Relator-Plaintiff believes and therefore avers that Shire has used inappropriate inducements (i.e. payments to physicians) to improperly promote Adderall XR and Vyvanse.



**COUNT I**  
**Violations of False Claims Act**  
**31 U.S.C. § 3729**

64. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

65. This Count is brought by Relator-Plaintiff in the name of the United States against the Defendant under the *qui tam* provisions of 31 U.S.C. § 3730 for Defendant's violation of 31 U.S.C. § 3729(a)(1) and (a)(2). In violation of 31 U.S.C. § 3729(a)(1) and (a)(2), Defendant made and caused to be made, the false claims that have been set forth in the Complaint herein.

66. Plaintiff United States, unaware of the falsity of the claims and/or statements which Defendant caused doctors, pharmacists, and other health care providers to make to the United States, and in reliance on the accuracy thereof, paid those doctors, pharmacies and other health care providers for claims that would otherwise not have been allowed.

67. The amounts of the false or fraudulent claims to the United States were material.

68. Plaintiff United States, being unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy thereof, paid and may continue to pay Defendant for health care services that otherwise should not have been paid under the Medicaid, CHAMPUS/TRICARE, CHAMPVA, and the Federal Health Benefit Program, and other federal health care programs.

69. The United States and the state Medicaid programs have been damaged by the payment of false or fraudulent claims.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

a. That by reason of the aforementioned violations of the False Claims Act this Court enter judgment in Plaintiff's favor and against Shire in an amount equal to three (3) times the amount of damages that the United States has sustained because of Shire's actions, plus

a civil penalty not less than \$5,000 nor more than \$10,000 for each violation of 31 U.S.C. § 3729;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act and/or any other applicable provision of the law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff-Relator has such other and further relief that this Court deems just and proper.

**COUNT III**  
**California False Claims Act**  
**Cal. Government Code §§ 12650-12655**

70. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

71. This is a claim against Shire for treble damages and penalties on behalf of the State of California under the California False Claims Act, California Government Code §§ 12650-12655.

72. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

73. By virtue of the above-described unlawful acts, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims under the Medicaid program.

74. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

75. By reason of Defendant's conspiracy and unlawful acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

76. The State of California is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

a. That by reason of the aforementioned violations of the California False Claims Act that this Court enter judgment in Plaintiff's favor and against Shire in an amount equal to not less than two times and not more than three times the amount of damages that California has sustained because of Shire's actions, plus a civil penalty of not more than \$10,000 for each violation of CAL. GOV. CODE §12651(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to CAL. GOV. CODE §12652(g)(2) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT IV**  
**Delaware False Claims and Reporting Act**  
**6 Del C. §1201(a)(1) and (2)**

77. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

78. This is a claim for treble damages and penalties against Shire on behalf of the State of Delaware under the Delaware False Claims and Reporting Act, 6 Del C. §1201(a)(1) and (2).

79. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

80. By virtue of the above-described acts, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

81. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

82. By reason of Defendant's conspiracy and unlawful acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

83. The State of Delaware is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

a. That by reason of the aforementioned violations of the Delaware false claims provisions that this Court enter judgment in Plaintiff's favor and against Shire in an amount equal to not less than two times and not more than three times the amount of damages that Delaware has sustained because of Shire's actions, plus a civil penalty of not less than \$5,500 and not more than \$11,000 for each violation of DEL. CODE ANN. TIT. 6 §1201(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to DEL. CODE ANN. §1205(a) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

#### **COUNT V**

#### **District of Columbia Procurement Reform Amendment Act Violation of D.C. CODE ANN. §§ 2-308.13-.15**

84. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

85. This is a claim for treble damages and penalties against Shire on behalf of the District of Columbia under the District of Columbia Procurement Reform Amendment Act.

86. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

87. By virtue of the above-described acts, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.



88. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

89. By reason of the Defendant's unlawful acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

90. The District of Columbia is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

a. That by reason of the aforementioned violations of the District of Columbia false claims provisions that this Court enter judgment in Plaintiff's favor and against Shire in an amount equal to not less than two times and not more than three times the amount of damages that the District of Columbia has sustained because of Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of DC. CODE ANN. §2-308.14(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant DC. CODE ANN. §2-308.15(f)(1) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT VI**  
**Florida False Claims Act**  
**Fl. Stat. §68.081-68.090**

91. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

92. This is a claim for treble damages and penalties against the Defendant on behalf of the State of Florida under the Florida False Claims Act, Fl.Stat. §68.081-68.090.

93. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

94. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

95. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

96. By reason of the Defendant's unlawful acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

97. The State of Florida is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

a. That by reason of the aforementioned violations of the Florida false claims provisions that this Court enter judgment in Plaintiff's favor and against Shire in an amount

equal to not less than two times and not more than three times the amount of damages that Florida has sustained because of Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of FLA. STAT. ANN. §68.082(2)(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant FLA. STAT. ANN. §68.085(1)-(2) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT VII**  
**Hawaii False Claims Act**  
**HAW. REV. STAT. §§661-21 to 661-29**

98. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

99. This is a claim for treble damages and penalties against the Defendant on behalf of the State of Hawaii under the HAW. REV. STAT. §661-21(a)(3).

100. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

101. By virtue of the above-described acts, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

102. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

103. By reason of the Defendant's unlawful acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

104. The State of Hawaii's Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

- a. That by reason of the aforementioned violations of the Hawaii's false claim provisions that this Court enter judgment in Plaintiff's favor and against Shire in an amount equal to not less than two times and not more than three times the amount of damages that Hawaii has sustained because of Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of HAW. REV. STAT. §661-21(a)(3);
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant HAW. REV. STAT. §661-27(a) and/or any other applicable provision of law;
- c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT VIII**  
**Illinois Whistleblower Reward and Protection Act**  
**740 ILCS 175/1 *et seq.***

105. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

106. This is a claim for treble damages and penalties against the Defendant on behalf of the State of Illinois under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175/1 *et seq.*

107. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

108. By virtue of the above-described acts, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

109. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

110. By reason of the Defendant's unlawful acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

111. The State of Illinois is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:



a. That by reason of the aforementioned violations of the Illinois Whistleblower Reward and Protection Act that this Court enter judgment in Plaintiff's favor and against Shire in an amount equal to not less than two times and not more than three times the amount of damages that Illinois has sustained because of Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of ILL. COMP. STAT. 175/3(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant ILL. COMP. STAT. 175/4(d)(1) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT IX**  
**Nevada False Claims Act**  
**NEV. REV. STAT. ANN. §357.01-.250**

112. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

113. This is a claim for treble damages and penalties against the Defendant on behalf of the State of Nevada under the Nevada False Claims Act. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FD

114. By virtue of the above-described acts, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

115. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

116. By reason of the Defendant's unlawful acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

117. The State of Nevada is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

- a. That by reason of the aforementioned violations of the Nevada false claims provisions that this Court enter judgment in Plaintiff's favor and against Shire in an amount equal to not less than two times and not more than three times the amount of damages that Nevada has sustained because of Shire's actions, plus a civil penalty of not more than \$10,000 for each violation of the NEV. REV. STAT. ANN. §357.014(1)(c);
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant Nev. Rev. Stat. Ann. §357,210(1) and/or any other applicable provision of law;
- c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT X**  
**Tennessee Medicaid False Claims Act**  
**Tenn. Code. Ann. §71-5-181 to -185**

118. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

119. This is a claim for treble damages and penalties against the Defendant on behalf of the State of Tennessee under the Tennessee Medicaid False Claims Act.

120. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

121. By virtue of the above-described acts, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

122. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

123. By reason of the Defendant's unlawful acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

124. The State of Tennessee is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

a. That by reason of the aforementioned violations of the Tennessee false claims provisions that this Court enter judgment in Plaintiff's favor and against Shire in an amount equal to not less than two times and not more than three times the amount of damages that Tennessee has sustained because of Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of the TENN. CODE ANN. §71-5-182(a)(1)(C);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant Tenn. Code. Ann. §71-5-183(c)(1) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT XI**  
**Texas Medicaid Fraud Prevention Act**  
**TEX. HUM. RES. CODE ANN 36.001-.132**

125. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

126. This is a claim for treble damages and penalties against the Defendant on behalf of the State of Texas under the Texas Medicaid Fraud Prevention Act, TEX. HUM. RES. CODE ANN.36.001-.132.

127. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

128. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

129. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

130. By reason of the Defendant's unlawful acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

131. The State of Texas is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

a. That by reason of the aforementioned violations of the Texas Medicaid Fraud Prevention Statute that this Court enter judgment in Plaintiff's favor and against Shire in an amount equal to two times the amount of damages that the state of Texas has sustained because of Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$15,000 fore each violation of TEX. HUM. RES. CODE ANN. § 36.002(8) that results in injury to an elderly person, a disabled person, or a person younger than 18 years of age, or not less than \$1,000 and not more than \$10,000 for each violation of the TEX. HUM. RES. CODE ANN. § 36.002(8) that does not result in an injury to a person;



b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant TEX. HUM. RES. CODE ANN. § 36.110 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT XII**  
**VIRGINIA FRAUD AGAINST TAXPAYERS ACT**  
**VA. CODE ANN. 8.01-216.1-216.19**

132. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

133. This is a claim for treble damages and penalties against the Defendant on behalf of the Commonwealth of Virginia under the Virginia Fraud Against Taxpayers Act, Vested. Ch. 842, Article 19.1, § 8.01-216.1 *et seq.*

134. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

135. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

136. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

137. By reason of the Defendant's unlawful acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

138. The State of Virginia is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

- a. That by reason of the aforementioned violations of the Virginia Fraud Against Taxpayers Act that this Court enter judgment in Plaintiff's favor and against Shire in an amount equal to not less than two times and not more than three times the amount of damages that the Commonwealth of Virginia has sustained because of Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of the VA. CODE ANN. § 8.01-216.3(A)(3);
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant VA. CODE ANN. § 8.01-216.7 and/or any other applicable provision of law;
- c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT XIII**  
**Georgia State False Medicaid Claims Act**  
**Ga. Code 49-4-168 *et seq.***

139. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

140. This is a claim for treble damages and penalties against the Defendant on behalf of the State of Georgia under the Georgia State False Medicaid Claims Act, Ga. Code 49-4-168 *et seq.*

141. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

142. By virtue of the above-described acts, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

143. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

144. By reason of the Defendant's unlawful acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

145. The State of Georgia is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

a. That by reason of the aforementioned violations of the Georgia False Medicaid Claims Act that this Court enter judgment in Plaintiff's favor and against Shire in an amount equal to not less than two times and not more than three times the amount of damages

that the Georgia has sustained because of Shire's actions, plus a civil penalty of not more than \$10,000 for each violation of the GA. CODE ANN. § 49-4-168.1;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant the GA. CODE ANN. § 49-4-168.2 (I) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT XIV**

**Violation of the Indiana State False Claims and Whistleblowers Protection Act, IND. CODE ANN. § 5-11-5.5-1 – 5-11-5.5-18**

146. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

147. This is a claim for treble damages and penalties against the Defendant on behalf of the State of Indiana under the Indiana State False Claims and Whistleblowers Protection Act, IND. CODE ANN. § 5-11-5.5-1 – 5-11-5.5-18.

148. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

149. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

150. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

151. By reason of the Defendant's unlawful acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

- a. That by reason of the aforementioned violations of the Indiana State False Claims and Whistleblowers Protection Act that this Court enter judgment in Plaintiff's favor and against Shire in an amount equal to not less than two times and not more than three times the amount of damages that the Indiana has sustained because of Shire's actions, plus a civil penalty of less than \$5,000 for each violation of the IND. CODE ANN. § 5-11-5.5-2;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant the IND. CODE ANN. § 5-11-5.5-6 and/or any other applicable provision of law;
- c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT XV**  
**Violation of the Michigan Medicaid False Claims Act**  
**MICH. COMP LAWS § 400.601-400.613**

152. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.



153. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

154. By virtue of the above-described acts, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

155. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

156. By reason of the Defendant's unlawful acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

157. The Michigan State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

a. That by reason of the aforementioned violations of the Michigan State Medicaid False Claims Act that this Court enter judgment in Plaintiff's favor and against Shire in an amount equal to three times the amount of damages that the Michigan has sustained because of Shire's actions, plus a civil penalty of equal to the full amount Shire unjustly received as a result of its unlawful conduct for violating MICH. COMP LAWS § 400.603, 606 and 607;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant the MICH. COMP LAWS § 400.610 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT XVI**  
**Violation of the Montana False Claims Act**  
**MONT. CODE ANN. § 17-8-401 – 17-8-412**

158. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

159. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

160. By virtue of the above-described acts, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.

161. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

162. By reason of the Defendant's unlawful acts, the State of Montana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

163. The Montana State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

a. That by reason of the aforementioned violations of the Montana False Claims Act that this Court enter judgment in Plaintiff's favor and against Shire in an amount equal to not less than two times and not more than three times the amount of damages that the Montana has sustained because of Shire's actions, plus a civil penalty of not more than \$10,000 for each violation of the MONT. CODE ANN. § 17-8-403;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant the MONT. CODE ANN. § 17-8-410 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT XVII**  
**New Hampshire False Claims Act**  
**N.H. REV. STAT. ANN. § 167:58-167:61-b**

164. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

165. This is a claim for treble damages and penalties against Defendants on behalf of the State of New Hampshire under the New Hampshire False Claims Act, N.H. REV. STAT. ANN. §167:61-b.

166. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

167. By virtue of the above-described acts, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

168. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

169. By reason of the Defendant's unlawful acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

170. The State of New Hampshire is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

a. That by reason of the aforementioned violations of the New Hampshire false claims provisions that this Court enter judgment in Plaintiff's favor and against Shire in an amount equal to not less than two times and not more than three times the amount of damages that New Hampshire has sustained because of Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of the N.H. REV. STAT. ANN. §167:61-b;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant N.H. REV. STAT. ANN. §167:61-b and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT XVIII**  
**New Mexico Medicaid False Claims Act,**  
**N.M. STAT. ANN. § 27-14-1- - 27-14-15**

171. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

172. This is a claim for treble damages and penalties against all Defendant on behalf of the State of New Mexico under the New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-14-1- 27-14-15.

173. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

174. By virtue of the above-described acts, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

175. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

176. By reason of the Defendant's unlawful acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:



a. That by reason of the aforementioned violations of the New Mexico False Claims Act provisions that this Court enter judgment in Plaintiff's favor and against Shire in an amount three times the amount of damages that New Mexico has sustained because of Shire's actions for violation of the N.M. STAT. ANN. § 27-14-4;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant N.M. STAT. ANN. § 27-14-9 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT XIX**  
**New York False Claims Act**  
**N.Y. St. Finance Law §187 *et seq.***

177. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

178. This is a claim for treble damages and penalties against all Defendant on behalf of the State of New York under the New York False Claims Act, N.Y. St. Finance Law §187 *et seq.*

179. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

180. By virtue of the above-described acts, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

181. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

182. By reason of the Defendant's unlawful acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

183. The State of New York is entitled to the maximum penalty of \$12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

- a. That by reason of the aforementioned violations of the New York False Claims Act provisions that this Court enter judgment in Plaintiff's favor and against Shire in an amount equal to not less than two times and not more than three times the amount of damages that New York has sustained because of Shire's actions, plus a civil penalty of not less than \$6,000 and not more than \$12,000 for each violation of N.Y. STATE FIN. LAW § 189;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant N.Y. STATE FIN. LAW § 119(6) and/or any other applicable provision of law;
- c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT XX**  
**Louisiana Medical Assistance Programs Integrity Law**  
**Louisiana Rev. Stat. §437 *et seq.***

184. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

185. This is a claim for treble damages and penalties against all Defendant on behalf of the State of Louisiana under the Louisiana Medical Assistance Programs Integrity Law, Louisiana Rev. Stat. §437 *et seq.*

186. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

187. By virtue of the above-described acts, Defendant knowingly made, used, or Louisiana State Government to approve and pay such false and fraudulent claims.

188. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

189. By reason of the Defendant's unlawful acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

a. That by reason of the aforementioned violations of the New Mexico False Claims Act provisions that this Court enter judgment in Plaintiff's favor and against Shire in an amount three times the amount of damages that Louisiana has sustained because of Shire's actions for violation of the Louisiana Medical Assistance Programs Integrity Law, Louisiana Rev. Stat. §437 *et seq.*;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant Louisiana Medical Assistance Programs Integrity Law, Louisiana Rev. Stat. §437 *et seq.* and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT XXI**  
**Massachusetts False Claims Act**  
**Massachusetts Gen. Laws c.12 §5(A)**

190. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

191. This is a claim for treble damages and penalties against the Defendant on behalf of the Commonwealth of Massachusetts under the Massachusetts False Claims Act, Massachusetts Gen. Laws c.12 §5(A).

192. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

193. By virtue of the above-described acts, Defendant knowingly made, used, or caused the Commonwealth of Massachusetts to approve and pay such false and fraudulent claims.

194. The Commonwealth of Massachusetts, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

195. By reason of the Defendant's unlawful acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

- a. That by reason of the aforementioned violations of the Massachusetts False Claims Act provisions that this Court enter judgment in Plaintiff's favor and against Shire in an amount three times the amount of damages that Louisiana has sustained because of Shire's actions for violation of the Massachusetts False Claims Act, Massachusetts Gen. Laws c.12 §5(A);
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant Massachusetts False Claims Act, Massachusetts Gen. Laws c.12 §5(A) and/or any other applicable provision of law;
- c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT XXIII**  
**New York City False Claims Act**  
**New York City Administrative Code §7-801-§7-810**

196. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

197. This is a claim for treble damages and penalties against the Defendant on behalf of the City of New York under the New York City False Claims Act, New York City Administrative Code §7-801-§7-810.

198. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.



199. By virtue of the above-described acts, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York City Government to approve and pay such false and fraudulent claims.

200. The New York City Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

201. By reason of the Defendant's unlawful acts, the City of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

a. That by reason of the aforementioned violations of the New York City False Claims Act provisions that this Court enter judgment in Plaintiff's favor and against Shire in an amount equal to not less than two times and not more than three times the amount of damages that the City of New York has sustained because of Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$15,000 for each violation of the New York City False Claims Act, New York City Administrative Code §7-801-§7-810;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant New York City Administrative Code § 704(i) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**COUNT XXIV**  
**City of Chicago False Claims Act**  
**Municipal Code of Chicago §1-22-010-§1-22-060**

202. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

203. This is a claim for treble damages and penalties against all Defendant on behalf of the City of Chicago under the Chicago False Claims Act, Municipal Code of Chicago §1-22-010-§1-22-060.

204. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

205. By virtue of the above-described acts, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Chicago City Government to approve and pay such false and fraudulent claims.

206. The Chicago City Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

207. By reason of the Defendant's unlawful acts, the City of Chicago has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

**COUNT XXV**  
**New Jersey False Claims Act**  
**N.J. STAT. §2A:32C-1-17**

208. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

209. This is a claim for treble damages and penalties against the Defendant on behalf of the State of New Jersey under the New Jersey False Claims Act N.J. STAT. §2A:32C-1-17.

210. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA approved labeling.

211. By virtue of the above-described acts, Defendant knowingly made, used, or cause the State of New Jersey to approve and pay such false and fraudulent claims.

212. The State of New Jersey, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

213. By reason of the Defendant's unlawful acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

WHEREFORE, Plaintiff demands judgment against defendant Shire as follows:

a. That by reason of the aforementioned violations of the New Jersey False Claims provisions that this Court enter judgment in Plaintiff's favor and against Shire in an amount equal to not less than two times and not more than three times the amount of damages that the state of New Jersey has sustained because of Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of N.J. STAT. §2A:32C-1-17;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant N.J. STAT. §2A:32C-1-17 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

**PRAYER FOR RELIEF**

WHEREFORE, Relator-Plaintiff Gerardo Torres, M.D. and plaintiff United States prays for judgment against Defendant Shire as follows:

a. That Defendant be found to have violated and be enjoined from future violations of the Federal False Claims Act, 31 U.S.C. §3729 *et seq.*;

b. That this Court enter judgment against defendant Shire in an amount equal to three times the amount of damages the United States Government has sustained because of defendant Shire's false or fraudulent claims, plus the maximum civil penalty for each violation of 31 U.S.C. §3729;

c. That this Court enter judgment against defendant Shire in an amount equal to three times the amount of damages the State of California has sustained because of defendant Shire's actions, plus a civil penalty of not more than \$10,000 for each violation of CAL. GOV. CODE §12651(a)(3);

d. That this Court enter judgment against defendant Shire in an amount equal to three times the amount of damages the State of Delaware has sustained because of defendant Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$11,000 for each violation of 6 DEL. CODE ANN. TIT. 6, §1201(a)(3);

e. That this Court enter judgment against defendant Shire in an amount equal to three times the amount of damages the District of Columbia has sustained because of defendant Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of D.C. CODE ANN. §2-3-8.14(a)(3);

f. That this Court enter judgment against defendant Shire in an amount equal to three times the amount of damages the State of Florida has sustained because of defendant Shire's actions, plus a civil penalty of \$11,000 for each violation of FLA. STAT ANN. §68.082(2)(a)(3);

g. That this court enter judgment against defendant Shire in an amount equal to not less than two times and not more than three times the amount of damages the state of Hawaii has sustained because of defendant Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of HAW. REV. STAT. §661-21-(a)(3);

h. That this Court enter judgment against defendant Shire in an amount equal to three times the amount of damages the State of Illinois has sustained because of defendant Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of 740 ILL. COMP. STAT. §175/3(a)(3);

i. That this court enter judgment against defendant Shire in an amount equal to not less sustained because of Shire's actions, plus a civil penalty of not more than \$10,000 for each violation of the IND. CODE ANN. § 5-11-5.5-2;

j. That this Court enter judgment against defendant Shire in an amount equal to three times the amount of damages the State of Louisiana has sustained because of defendant Shire's actions, plus a civil penalty to the full amount Defendant unjustly received as a result of unlawful conduct for violating Louisiana Medical Assistance Programs Integrity Law, Louisiana Rev. Stat. §437 *et seq.*;

k. That this Court enter judgment against defendant Shire in an amount equal to three times the amount of damages the Commonwealth of Massachusetts has sustained because of defendant Shire's actions, plus a civil penalty to the full amount Defendant unjustly received



as a result of unlawful conduct for violating Massachusetts False Claims Act, Massachusetts Gen. Laws c.12 §5(A);

l. That this Court enter judgment against defendant Shire in an amount equal to three times the amount of damages the State of Michigan has sustained because of defendant Shire's actions, plus a civil penalty to the full amount Defendant unjustly received as a result of unlawful conduct for violating MICH. COMP LAWS § 400.603, 606 and 607;

m. That this Court enter judgment against defendant Shire against Shire in an amount equal to not less than two times and not more than three times the amount of damages that Montana has sustained because of defendant Shire's actions, plus a civil penalty of not more than \$10,000 for each violation of the MONT. CODE ANN § 17-8-403;

n. That this Court enter judgment against defendant Shire in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of defendant Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for violation of N.H. REV. STAT. ANN. §167:61-b;

o. That this court enter judgment in Plaintiff's favor and against defendant Shire in an amount three times the amount of damages that the State of New Mexico has sustained because of Shire's actions for violation of N.M. STAT. ANN. § 27-14-4;

p. That this Court enter judgment against defendant Shire in an amount equal to three times the amount of damages the State of Nevada has sustained because of defendant Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of the Nevada False Claims Act;

q. That this Court enter judgment against defendant Shire in an amount equal to three times the amount of damages the City of New York has sustained because of defendant



Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$15,000 for each violation of the New York City False Claims Act;

r. That this Court enter judgment against defendant Shire in an amount equal to three times the amount of damages the City of Chicago has sustained because of defendant Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of the Chicago False Claims Act;

s. That this Court enter judgment against defendant Shire in an amount equal to three times the amount of damages the State of Tennessee has sustained because of defendant Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of the Tennessee Medicaid False Claims Act;

t. That this Court enter judgment against defendant Shire in an amount equal to the damages that the state of Texas has sustained because of defendant Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$15,000 fore each violation of TEX. HUM. RES. CODE ANN. § 36.002(8) that results in injury to an elderly person, a disabled person, or a person younger than 18 years of age, or not less than \$1,000 and not more than \$10,000 for each violation of TEX. HUM. RES. CODE ANN. § 36.002(8) that does not result in an injury to a person;

u. That this Court enter judgment against defendant Shire in an amount equal to three times the amount of damages the State of Virginia has sustained because of defendant Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of Va. Code Ann. §8.01-216.3(a)(1), (2);

v. That this Court enter judgment against defendant Shire in an amount equal to three times the amount of damages the State of Georgia has sustained because of a Defendant's

actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of GA. CODE 49-4-168.1;

w. That this Court enter judgment against defendant Shire in an amount equal to three times the amount of damages the State of Indiana has sustained because of defendant Shire's actions, plus a civil penalty of not less than \$5,000 for each violation of IND. CODE ANN. §5-11-5.5-2;

x. That this Court enter judgment against defendant Shire in an amount equal to three times the amount of damages the State of New York has sustained because of defendant Shire's actions, plus a civil penalty of not less than \$6,000 and not more than \$12,000 for each violation of N.Y. STATE FIN. LAW §189;

y. That this Court enter judgment against defendant Shire in an amount equal to not less than two times and not more than three times the amount of damages that the state of New Jersey has sustained because of Shire's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of N.J. STAT. §2A:32C-1-17

z. That Relator-Plaintiff be awarded the maximum amount allowed pursuant to §3730(d) of the Federal False Claims Act, and the equivalent provisions of the state statutes set forth above;

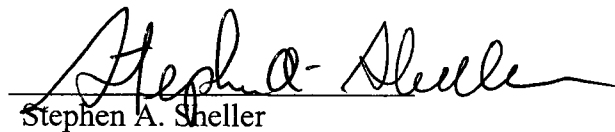
aa. That Relator-Plaintiff be awarded all costs of this action, including attorneys' fees and expenses; and

bb. That Relator-Plaintiff recover such other relief as the Court deems just and proper or that is necessary to make Relator-Plaintiff whole.

**Demand for Jury Trial**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff hereby demands a trial by jury.

Respectfully submitted,



Stephen A. Sheller  
Brian J. McCormick, Jr.  
James J. Pepper  
SHELLER, P.C.  
1528 Walnut Street, Floor 3  
Philadelphia, PA 19102  
(215)790-7300

Attorneys for Relator-Plaintiff Gerardo Torres,  
M.D.

DATE: October 7, 2008

**FILED**  
**OCT 7 2008**  
By MICHAEL C. [Signature] Clerk  
Deputy

PD

APPENDIX I

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

**CASE MANAGEMENT TRACK DESIGNATION FORM**

Gerardo Torres MD, ex rel.

United States

v.

Shire, et al.

CIVIL ACTION

08 4795

NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a case management track designation form specifying the track to which that defendant believes the case should be assigned.

**SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:**

- (a) Habeas Corpus – Cases brought under 28 U.S.C. §2241 through §2255. ( )
- (b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits ( )
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (x)
- (f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

10/7/08

Date

JAMES J. PEPPER

Attorney-at-law

GERARDO TORRES

Attorney for

215-790-7300

Telephone

215-546-0942

FAX Number

JPEPPER@SHELLER.COM

E-Mail Address

OCT - 7 2008

JS 44 (Rev. 12/07)

## CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings on other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

## I (a) PLAINTIFFS

Gerardo Torres, MD ex rel United States

(b) County of Residence of First Listed Plaintiff Bucks  
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

Stephen A. Sheller, Esq., 1528 Walnut Street  
Philadelphia, PA 19102

## DEFENDANTS

See attached

County of Residence of First Listed Defendant Delaware  
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

## II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☒ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

## III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- |   | PTF                        | DEF                        |   | PTF                        | DEF                        |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State                   | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business in This State     | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State                | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business in Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation  | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

## IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veterans' Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	<b>PERSONAL INJURY</b> <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	<b>PERSONAL PETITIONS</b> <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition	<b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	<input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609
			<b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input checked="" type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes

## V. ORIGIN

(Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from another district (specify)
- ☐ 6 Multidistrict Litigation
- ☐ 7 Appeal to District Judge from Magistrate Judgment

## VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

310 U.S.C. § 3729 et seq.

Brief description of cause:  
Quilliam Action

## VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☐ Yes ☐ No

## VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

DATE

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE

OCT - 7 2008

**Defendants:**

**Shire Specialty Pharmaceuticals**

**Shire PLC**

**Shire US, Inc.**

**Shire Pharmaceuticals**

**Shire, LLC**

**Shire Development**

**Shire US Manufacturing, Inc.**



UNDER SEAL

UNITED STATES DISTRICT COURT

08 4795

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: Gerardo Torres, MD, ex rel United States 2 Bayshore Dr., Newtown, PA 18910

Address of Defendant: Shire 725 Chesterbrook Blvd. Wayne, PA 19087

Place of Accident, Incident or Transaction: Qui Tam Action

(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a))

Yes ☐

No ☒

Does this case involve multidistrict litigation possibilities?

Yes ☐

No ☒

RELATED CASE, IF ANY:

Case Number: Judge Date Terminated:

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?

Yes ☐

No ☒

2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?

Yes ☐

No ☒

3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court?

Yes ☐

No ☒

4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?

Yes ☐

No ☒

CIVIL: (Place ☒ in ONE CATEGORY ONLY)

A. Federal Question Cases:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts

2. ☐ FELA

3. ☐ Jones Act-Personal Injury

4. ☐ Antitrust

5. ☐ Patent

6. ☐ Labor-Management Relations

7. ☐ Civil Rights

8. ☐ Habeas Corpus

9. ☐ Securities Act(s) Cases

10. ☐ Social Security Review Cases

11. ☒ All other Federal Question Cases  
(Please specify)

Qui Tam

B. Diversity Jurisdiction Cases:

1. ☐ Insurance Contract and Other Contracts

2. ☐ Airplane Personal Injury

3. ☐ Assault, Defamation

4. ☐ Marine Personal Injury

5. ☐ Motor Vehicle Personal Injury

6. ☐ Other Personal Injury (Please specify)

7. ☐ Products Liability

8. ☐ Products Liability — Asbestos

9. ☐ All other Diversity Cases

(Please specify)

ARBITRATION CERTIFICATION

(Check appropriate Category)

I, James J. Pepper (SHELLER, P.C.), counsel of record do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

DATE: 10/7/08

Attorney-at-Law

92614

Attorney I.D.#

OCT - 7 2008

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court